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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,993	03/19/2004	Kurt Amplatz	20030372.ORI	8936
23595	7590	11/14/2006		
NIKOLAI & MERSEREAU, P.A. 900 SECOND AVENUE SOUTH SUITE 820 MINNEAPOLIS, MN 55402			EXAMINER FOSTER, MARLEE CHRISTINE	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,993

Applicant(s)

AMPLATZ ET AL.

Examiner

Marlee C. Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/10/2004, 02/03/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 3, 7, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Amplatz (U.S. Patent 6,368,339). Amplatz discloses a collapsible medical device shaped to occlude an abnormal opening in a vascular organ, comprising an outer metal fabric surrounding an inner metal fabric, each having a plurality of braided metal strands with an expanded preset configuration and proximal and distal ends. The ends have a means for independently securing the plurality of braided strands together in a clamp (figure 6C, reference 15). As Amplatz discloses, the device is composed of nitinol, a shape memory alloy, which allows it to deform to a smaller cross-section area for insertion through a conduit, and then return to its expanded preset configuration (col. 2, lines 28-30 and col. 4, lines 15-56).

3. Regarding claim 2, the pitch of the braided metal strands is disclosed to be 50 degrees, and is generally equal throughout (figure 6C). Regarding claim 3, the braided metal strands of the outer fabric are of a larger diameter than the strands of the inner fabric (col. 7, lines 24-27).

4. Regarding claim 7, Amplatz discloses only two expanded diameter portions in the figures, but additionally discloses that the device may have three expanded diameter

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portions separated by a tubular portion having a smaller diameter (col. 10, lines 20-27).

Each diameter portion comprises a plurality of metal strands that may be expanded to a preset configuration.

5. Regarding claims 13 and 14, Amplatz discloses clamping the braided fabric at the proximal and distal ends, and discloses means of securing the braided metal strands by a molding element that compresses the braided fabrics (col. 13, lines 3-27).

Amplatz additionally discloses, in col. 10, lines 35-40, a vascular occlusion device that will engage with a lumen at the area of the largest diameter (the outer fabric) to prevent the occlusion device from moving within the lumen.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 4, 5, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz (US Patent 6,368,339) in view of Mazzocchi (U.S. Patent 6,168,622). Amplatz discloses a vascular occluding device wherein the pitch of the outer and inner layers is approximately 50 degrees (col. 3, line 65), and the pick of the device is about 74.

Regarding claims 4 and 5, Amplatz discloses, in col. 11, lines 28-33, that a greater wire density is desirable to allow the thrombi to collect on the increased surface area, thus increasing the occlusion of the device. However, Amplatz is silent as to the number of braided metal strands comprising the inner and outer metal fabrics. Mazzocchi teaches, a similar device with a pick of about 74 (col. 4, lines 60) and a 144-strand wire braid (col. 5, line 3 and col. 15, line 1). The increasing number of wires, as both Amplatz and Mazzocchi teach, increase the efficiency of the device and allow the device to anchor securely within the lumen. Therefore, it would have been obvious to one of ordinary skill in the art, to use a greater number of braided metal strands, as taught by Mazzocchi, to increase the efficiency of the braided occluding device of Amplatz.

Regarding claims 10 and 11, Amplatz discloses only two layers for the braided device, but suggests additional layers may be incorporated to increase the surface area and efficiency of the device. Mazzocchi teaches using a greater wire density, and a device with a wire density of 74, or, more preferably, 144 metal strands, to enhance the tendency of the device to occlude the aneurysm in which it is deployed by increasing the surface area for the thrombi to attach. Therefore, it would have been obvious to one of ordinary skill in the art, to use a greater number of braided metal strands, to enhance the thrombogenicity of the device.

10. Claims 6, 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz (US Patent 6,368,339) in view of Ken et al. (U.S. Patent 6,168,615). Amplatz discloses a collapsible medical device shaped to occlude an abnormal opening in a vascular organ, comprising an outer metal fabric surrounding an inner metal fabric, each having a plurality of braided metal strands with an expanded preset configuration. Additionally, Amplatz discloses more than two layers on the device. Amplatz teaches a larger diameter of the braided metal strands used in the vasoocclusive device.

Regarding claims 6 and 12, Ken et al. teach a vasoocclusive device with a plurality of metal strands. Ken et al. teach that the cables of the device are 0.002 to 0.006 inches in diameter (col. 7, lines 46-67). This increases the thrombogenicity of the device by allowing it to maintain the diameter of the preset configuration within the vessel, yet increase the number of braided metal strands of both the inner and outer configurations. Therefore, it would have been obvious to one of ordinary skill in the art

to decrease the diameter of each braided metal strand so that the number of braided metal strands could be increased without changing the overall diameter of the device of Amplatz at its expanded configuration.

Regarding claim 8, the pitch of the device of Amplatz is equal on the inner and outer fabrics. The device would maintain a stable configuration, even when an additional layer is added, by having the pitch of the third layer equal the pitch of the inner and outer layers. Therefore, it would have been obvious to one of ordinary skill in the art to make the pitch of all of the layers equal, so that it may be securely expanded within the lumen.

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Amplatz (U.S. Patent 6,368,339) in view of Gainor et al. (U.S. Patent 6,911,037).

Amplatz discloses the invention substantially as claimed, comprising an outer metal fabric surrounding an inner metal fabric, each having a plurality of braided metal strands with an expanded preset configuration at proximal and distal ends. Amplatz additionally discloses that the device, when deployed in a vessel, will engage the lumen at the greatest diameter. However, Amplatz is silent regarding the geometry of the outer layer with respect to the inner liner.

Gainor et al. teach, in figures 2 and 5, a first and second disk, with an inner and outer layer of differing geometrical shapes. The device of Gainor has "petals" of different geometrical shapes so that the frame of the occluding device will support the fabric when it is expanded within the lumen, and form over the septal defect (col. 7, lines 38-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time

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of the invention to provide the layers of the occluding device in differing geometrical shapes to maximize the strength of the device, and stabilize the layers within the lumen to prevent the device from moving.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lock et al. (U.S. Patent 5,709,707) and Amplatz (U.S. Patent 6,599,308) teach similar structural devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark C. Foster

mcf

[Signature]
ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

11/11/08